



Xeris Biopharma Subsidiaries File Recorlev® Patent Infringement Lawsuit

February 26, 2026

Four Orange Book Listed Patents through March 2040

Orphan Drug Exclusivity through December 2028

CHICAGO--(BUSINESS WIRE)--Feb. 26, 2026-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a fast-growing biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies, announced that its subsidiaries, Xeris Pharmaceuticals, Inc. and Strongbridge Dublin Limited, have filed a patent infringement lawsuit under the Hatch-Waxman Act related to Recorlev® (levoketoconazole) in the United States District Court for the District of New Jersey against Torrent Pharmaceuticals Limited (along with its affiliate) and Somerset Therapeutics, LLC (along with its affiliates), each of which filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration (the "FDA") seeking approval to manufacture, use or sell a generic version of Recorlev® (levoketoconazole) (each, an "ANDA Filer"). Xeris's complaint seeks an injunction to prevent the manufacture, use, and sale of a generic version of RECORLEV by each ANDA Filer until the expiration of Xeris's patents in March 2040.

"We are confident in the quality and strength of the intellectual property we have developed for Recorlev," said John P. Shannon, CEO of Xeris Biopharma. "We have filed this patent infringement lawsuit to vigorously defend our position."

The complaint was filed following receipt of Paragraph IV Certification Notice Letters from the ANDA Filers (each a "Notice Letter"). In its respective Notice Letter, each ANDA Filer alleged that the four patents covering Recorlev that are listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), scheduled to expire in March 2040 (U.S. Patent Numbers 11,020,393, 11,278,547, 11,903,940, and 12,377,096), are invalid, unenforceable, or will not be infringed by the respective ANDA Filer's commercial manufacture, use, or sale of the generic levoketoconazole product described in its ANDA submission.

Xeris may receive additional Notice Letters in the future from ANDA filers seeking approval of a generic version of Recorlev and intends to enforce and defend its intellectual property rights relating to Recorlev. Xeris Pharmaceuticals, Inc. and Strongbridge Dublin Limited are represented in this litigation by Latham & Watkins, LLP.

About Xeris

Xeris (Nasdaq: XERS) is a fast-growing biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products: Recorlev®, for the treatment of endogenous Cushing's syndrome; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia; and Keveyis®, a proven therapy for primary periodic paralysis. Xeris also has a pipeline of development programs led by XP-8121, a Phase 3-ready, once-weekly subcutaneous injection for hypothyroidism, as well as multiple early-stage programs leveraging Xeris' technology platforms, XeriSol® and XeriJect®, for its partners.

Xeris Biopharma Holdings is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on [X](#), [LinkedIn](#), or [Instagram](#).

Forward-Looking Statements

Any statements in this press release other than statements of historical fact are forward-looking statements. Forward-looking statements include, but are not limited to, statements about future expectations, plans, opportunities, and prospects for the Company, including statements, among other things, regarding its intention to enforce and defend its intellectual property rights relating to Recorlev®, including any expectations regarding the pending litigation, any plans to file a lawsuit against an ANDA filer in the future and the success or outcome of any such action, and its expectation that the Company will receive additional Notice Letters in the future. Because such statements are subject to risks and uncertainties, they constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of the Company's experience and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. No assurance can be given that such expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional risks and information about potential impacts of financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect the Company can be found in the Company's filings, including its most recently filed Annual Report on Form 10-K and subsequent filings with the U.S. Securities and Exchange Commission ("SEC"), the contents of which are not incorporated by reference into, nor do they form part of, this communication. The risks described herein and in the Company's SEC filings are not the only risks the Company faces. Additional risks and uncertainties not currently known to it or that it currently deems immaterial may also impact its business operations or financial results. Forward-looking statements in this report are based on information available to management, as of the date of this communication and, while the Company believes its assumptions are reasonable, actual results may differ materially. Subject to any obligations under applicable law, the Company does not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

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